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PhRMA

May 30, 2006

Dockets Management Branch
Food and Drug Administration
(HFA-305)
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2006N-0104; Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide the following comments on the above noted draft guidance. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industry-wide research and investment reached a record $51.3 billion in 2005.

In response to FDA's request for public comment on the reporting requirements contained in the "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (68 FR 69009, December 11, 2003) (the final rule) we wish to comment on the accuracy of FDA's estimate of the burden of the proposed collection of information.

FDA estimates that in each of three major categories of submissions (NDAs, Labeling supplements to the NDA, and NDA Annual Reporting) the additional reoccurring reporting burden associated with the electronic submission of the content of labeling is less than 15 minutes per submission. We believe that the FDA's estimate is not representative of the burden incurred by the sponsor as a result of these reporting requirements. As a result, we respectfully submit the following information collected from PhRMA member companies for consideration.

The April 2006 guideline specifically identifies Extensible Markup Language (XML) as the required file format for Structured Product Label documents (SPL), which is a relatively new format requiring an initial investment in software, training, and process change. Additionally, SPL cannot simply be converted from the Word or PDF version of a label. The process for creating the SPL includes significant effort in mapping, coding, recreation of the file, and quality control.

In general, sponsors are using one of two methods to prepare the SPL: internal creation using XML authoring software, or conversion of labeling into SPL format by an outside vendor. When using an outside vendor, preparation, hand-offs, and conversion can take days, and a high level of quality assurance is required. When using XML authoring software in-house to produce the SPL internally, there is the added effort and expense required to purchase, install, validate, and maintain specialized software. Once the system is established, the creation, verification, and inclusion of the SPL in the submission takes hours, not minutes, under best circumstances.

Whichever method is used, the time varies depending on the complexity of the labeling changes. For example, the initial conversion of the label requires the sponsor to obtain information necessary to populate the structured data elements (drug product information) that was not previously required prior to SPL implementation. This can take anywhere from 1 to 7 days, depending whether the elements have been encountered before. Recognizing that this work will decrease due to the learning curve, the time required for this effort is not included in the time estimates below.

The time estimates provided below include a range from low to high. The lower value indicates time taken for a small labeling submission that may add or change a few words or small amount of data. The higher value indicates time taken for a large or complex change that may involve inclusion of new data, a new indication, or new sections in the label as well as revised drug listing information. Please note that these figures indicate hours of effort and not days elapsed.

We respectfully submit the following estimates based on metrics collected from PhRMA member companies:

SPL Creation using Vendor conversion services: 34 to 66 hours
This time breaks down as follows:

- Average time spent by vendor: 16.75 to 32.75 hours
- Additional time spent by sponsor 17.25 to 33.25 hours

SPL Creation using XML authoring software: 5.75 to 9.0 hours

Given that the figures above are considerably different from the FDA's estimate, we request that the FDA revise their figures to more closely represent the burden associated with the electronic submission of the content of labeling.

Sincerely,

Alan.Goldhammer

Alan.Goldhammer
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For Demonstration Purposes